

**INTEGRITY AGREEMENT
BETWEEN THE OFFICE OF INSPECTOR GENERAL
OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
PEDIATRIC AND ADOLESCENT HEALTHCARE**

I. PREAMBLE

Pediatric and Adolescent Healthcare (PAH) hereby enters into this Integrity Agreement (Agreement) with the Office of Inspector General (OIG) of the United States Department of Health and Human Services (HHS) to promote compliance by PAH's owners, officers, directors, associates, employees, contractors, and agents with the statutes, regulations, program requirements, and written directives of Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) (Federal health care program requirements). This commitment to promote compliance applies to any entity that PAH owns or in which PAH has a control interest, as defined in 42 U.S.C. § 1320a-3(a)(3), and PAH's and any such entity's Covered Persons as defined in Section II.C. Contemporaneously with this Agreement, PAH is entering into a Settlement Agreement with the United States, and this Agreement is incorporated by reference into the Settlement Agreement.

II. TERM OF THE AGREEMENT

A. The period of compliance obligations assumed by PAH under this Agreement shall be three years from the effective date of this Agreement. The date on which the final signatory of this Agreement executes this Agreement shall be known as the Effective Date. Each one-year period beginning with the one-year period following the Effective Date shall be referred to as a "Reporting Period."

B. Sections VII, VIII, IX, X, and XI shall expire no later than 120 days from OIG's receipt of: (1) PAH's final Annual Report; or (2) any additional materials submitted by PAH pursuant to OIG's request, whichever is later.

C. The scope of this Agreement shall be governed by the following definitions:

1. "Covered Persons" includes:

a. all owners, officers, directors, associates, and employees of PAH; and

b. all contractors, agents, and other persons who provide patient care items or services or who perform billing or coding functions on behalf of PAH.

III. INTEGRITY OBLIGATIONS

PAH hereby agrees to establish a Compliance Program that, at a minimum, includes the following elements:

A. Compliance Contact

Within 30 days of the Effective Date of this Agreement, PAH shall designate a person to be responsible for compliance activities ("Compliance Contact"). PAH shall maintain a Compliance Contact for the term of this Agreement. The Compliance Contact shall be responsible for: (1) developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this Agreement and with Federal health care program requirements; (2) monitoring PAH's day-to-day compliance activities; and (3) meeting all reporting obligations created under this Agreement.

PAH shall report to OIG, in writing, any changes in the identity or job responsibilities of the Compliance Contact, or any actions or changes that would affect the Compliance Contact's ability to perform the duties necessary to meet the obligations in this Agreement, within 15 days after such change. The name, address, phone number, and a description of any other job responsibilities performed by the Compliance Contact shall be included in the Implementation Report.

B. Posting of Notice

Within 90 days after the Effective Date, PAH shall post in a prominent place accessible to all patients and Covered Persons a notice detailing its commitment to comply with all Federal health care program requirements in the conduct of its business.

This notice shall also include the following information: (1) a means (e.g., telephone number or address) by which instances of misconduct may be reported anonymously; (2) PAH's commitment to maintain the confidentiality of the report; and (3) notification that reporting a suspected

violation will not result in retribution or retaliation by PAH. A copy of this notice shall be included in the Implementation Report.

C. Written Policies and Procedures

Within 90 days after the Effective Date, PAH shall develop, implement, and distribute written Policies and Procedures to all Covered Persons. In addition, PAH shall make the promotion of, and adherence to, the written Policies and Procedures an element in evaluating the performance of all employees. The written Policies and Procedures shall, at a minimum, set forth:

1. PAH's commitment to full compliance with all Federal health care program requirements, including its commitment to prepare and submit accurate claims consistent with such requirements;
2. the expectation that all of PAH's Covered Persons shall be expected to comply with all Federal health care program requirements and with PAH's own written Policies and Procedures as implemented pursuant to this Section III.C (including the requirements of this Agreement);
3. the responsibility and requirement that all Covered Persons report suspected violations of any Federal health care program requirements or of PAH's own Policies and Procedures to the Compliance Contact and PAH's commitment to maintain confidentiality and anonymity, as appropriate, and not to retaliate with respect to such disclosures;
4. the possible consequences to both PAH and Covered Persons of failure to comply with Federal health care program requirements or with PAH's written Policies and Procedures and the failure to report such noncompliance;
5. PAH's commitment to remain current with all Federal health care program requirements by obtaining and reviewing program memoranda, newsletters, and any other correspondence from the carrier related to Federal health care program requirements;
6. the proper procedures for the accurate preparation and submission of claims in accordance with Federal health care program requirements; and

7. the applicable Federal health care program requirements relating to the management and accountability of vaccines under the Vaccines for Children Program, including, but not limited to, proper billing and payment procedures for vaccines.

Within 90 days after the Effective Date, each Covered Person shall certify in writing that he or she has received, read, understood, and shall abide by PAH's written Policies and Procedures. New Covered Persons shall receive and review the written Policies and Procedures and shall complete the required certification within 30 days after becoming a Covered Person or within 90 days after the Effective Date, whichever is later.

At least annually (and more frequently if appropriate), PAH shall assess and update, as necessary, the Policies and Procedures. Within 30 days after the effective date of any revisions, the relevant portions of any such revised Policies and Procedures shall be distributed to all Covered Persons. Appropriate and knowledgeable staff shall be available to explain the Policies and Procedures.

Copies of the written Policies and Procedures shall be included in the Implementation Report. Copies of any written Policies and Procedures that are subsequently revised shall be included in the next Annual Report along with a summary of any change or amendment to each Policy and Procedure required by this Section and the reason for each change.

D. Training and Certification

Within 90 days after the Effective Date and at least once each year thereafter, PAH and Covered Persons shall receive at least three hours of training from an individual or entity, other than another Covered Person. Persons providing the training shall be knowledgeable about the relevant subject area and may be received from a variety of sources (e.g., CME classes, hospitals, associations, carriers).

New Covered Persons shall receive the training described above within 30 days after becoming a Covered Person or within 90 days after the Effective Date, whichever is later. The training for new Covered Persons may either be provided internally by a Covered Person who has completed the required annual training or externally by a qualified individual or entity. A new Covered Person shall work under the direct supervision of a Covered Person who has received such training, to the extent that the work relates to the delivery of patient care items or services and/or the preparation or

submission of claims for reimbursement from any Federal health care program, until such time as the new Covered Person completes the training.

At a minimum, the initial, annual, and new employee training sessions shall include the following topics:

1. the requirements of PAH's Agreement;
2. an overview of PAH's compliance program;
3. the accurate coding and submission of claims for services rendered and/or items provided to Federal health care program beneficiaries;
4. applicable reimbursement statutes, regulations, and program requirements and directives;
5. the written Policies and Procedures developed pursuant to Section III.C, above;
6. the personal obligation of each individual involved in the coding and claims submission process to ensure that such claims are accurate;
7. the legal sanctions for the submission of improper claims or violations of the Federal health care program requirements;
8. examples of proper and improper coding and claim submission practices; and
9. the Federal health care program requirements relating to vaccine management and accountability under the Vaccines for Children Program, including, but not limited to, proper billing and payment procedures for vaccines.

Each Covered Person shall annually certify, in writing or in electronic format if the training is computerized, that he or she has received the required training. The certification shall specify the date the training was received. The Compliance Contact shall retain the certifications, along with all training materials. PAH shall annually review the training, and, where appropriate, update the training to reflect changes in Federal health care program requirements.

PAH may provide the training required under this Agreement through appropriate computer-based training approaches. If PAH chooses to provide computer-based training, it shall make available appropriately qualified and knowledgeable staff or trainers to answer questions or provide additional information to the individuals receiving such training.

The training materials shall be provided to the OIG in the Implementation Report, and to the extent the training is revised, shall also be included in the Annual Reports. The certifications shall be made available to OIG, upon request.

E. Management and Accountability of Vaccines

This Section III.E of the Agreement pertains specifically to vaccines received free of charge from the Vaccines for Children Program (hereinafter referred to as "Vaccines"). Within 90 days following the Effective Date of this Agreement, PAH shall assess its internal procedures relating to the management and accountability of Vaccines. If necessary, PAH shall establish and implement, or revise, internal procedures so they are reasonably designed to track the receipt, storage, inventory, use, and financial disposition of Vaccines.

As part of the Implementation Report, PAH shall describe the general procedures used to track the receipt, storage, use, inventory, and financial disposition of Vaccines. In addition, PAH shall report the following information:

1. the aggregate number of Vaccines received during the Reporting Period;
2. the entity or individual who provided each type of Vaccine;
3. the specific manner in which each Vaccine was used. For example, if PAH used the Vaccine to treat patients, PAH shall list the name of each patient, the source of the patient's insurance (if any), the number of Vaccines used to treat each patient, the date(s) of such use, and the manner in which the patient or any insurer was charged (if at all) for the sample. If the Vaccines were used to replace a damaged or expired product, PAH shall provide the number of Vaccines used in this manner, the date of the replacement, and the number of units of product, if any, returned to the manufacturer. If the Vaccines were used for training purposes, PAH shall identify to whom the training was provided, the date(s) on

which the training was provided, and how many Vaccines were used in providing such training. If PAH uses the Vaccines in any other manner, it shall describe, in detail, the manner in which those Vaccines were used; and

4. a certification by the Compliance Contact that PAH has complied with the applicable Federal health care program requirements relating to the management and accountability of Vaccines.

In the event the OIG has reason to believe that: (i) PAH's management and accountability of Vaccines fails to conform to the requirements of this Agreement; or (ii) the Vaccine information reported in accordance with this Section III.E is inaccurate, the OIG may, at its sole discretion, conduct its own review to determine whether PAH's management and accountability of Vaccines complies with the requirements of the Agreement and/or the Vaccine information reported pursuant to Section III.E is accurate ("Validation Review"). PAH agrees to pay for the reasonable cost of any such review performed by the OIG or any of its designated agents so long as it is initiated before one year after the final Annual Report is received by the OIG.

Prior to initiating a Validation Review, the OIG shall notify PAH of its intent to do so and provide a written explanation of why the OIG believes such a review is necessary. To resolve any concerns raised by the OIG, PAH may request a meeting with the OIG to discuss the underlying issues about PAH's compliance with the requirements of this Agreement, present any additional or relevant information, and/or propose alternatives to the proposed Validation Review. PAH agrees to provide any additional information as may be requested by the OIG under this section in an expedited manner. The OIG will attempt in good faith to resolve any Vaccine issues with PAH prior to conducting a Validation Review. However, the final determination as to whether or not to proceed with a Validation Review shall be made at the sole discretion of the OIG.

F. Ineligible Persons

1. Definitions. For purposes of this Agreement:

- a. An "Ineligible Person" shall include an individual or entity who:
 - i. is currently excluded, debarred, suspended, or otherwise ineligible to participate in the Federal health

care programs or in Federal procurement or nonprocurement programs; or

ii. has been convicted of a criminal offense that falls within the ambit of 42 U.S.C. § 1320a-7(a), but has not yet been excluded, debarred, suspended, or otherwise declared ineligible.

b. "Exclusion Lists" include:

i. the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at <http://oig.hhs.gov>); and

ii. the General Services Administration's List of Parties Excluded from Federal Programs (available through the Internet at <http://www.epls.arnet.gov>).

2. Screening Requirements. PAH shall ensure that all prospective and current owners, officers, directors, associates, employees, contractors, and agents of PAH are not Ineligible Persons. To ensure that such individuals and entities are not Ineligible Persons, PAH shall require such individuals and entities to disclose immediately any debarment, exclusion, suspension, or other event that makes such individual or entity an Ineligible Person. Prior to engaging the services of such individuals and entities, PAH shall screen such individuals and entities against the Exclusion Lists. In addition, PAH shall:

a. Within 90 days after the Effective Date, review its list of individuals and entities identified in Section III.F.2 against the Exclusion Lists; and

b. Review its list of individuals and entities identified in Section III.F.2 against the Exclusion Lists annually.

PAH shall maintain documentation demonstrating that: (i) it has checked the Exclusion Lists (e.g., print screens from search results) and determined that such individuals or entities are not Ineligible Persons; and (ii) has required individuals and entities to disclose if they are an Ineligible Person (e.g., employment applications). Nothing in this Section affects the responsibility of (or liability for)

PAH to refrain from billing Federal health care programs for services of the Ineligible Person.

3. Removal Requirement. If PAH has notice that any individual or entity in one of the positions identified in Section III.F.2 has become an Ineligible Person, PAH shall remove such individual or entity from responsibility for, or involvement with, PAH's business operations related to the Federal health care programs and shall remove such individual or entity from any position for which the individual's or entity's compensation or the items or services rendered, ordered, or prescribed by the individual or entity are paid in whole or in part, directly or indirectly, by Federal health care programs or otherwise with Federal funds at least until such time as the individual or entity is reinstated into participation in the Federal health care programs.

4. Pending Charges and Proposed Exclusions. If PAH has notice that an individual identified in Section III.F.2 is charged with a criminal offense that falls within the ambit of 42 U.S.C. § 1320a-7(a), or an individual or entity identified in Section III.F.2 is proposed for exclusion during his, her or its employment, involvement, or contract term, PAH shall take all appropriate actions to ensure that the responsibilities of that individual or entity has not and shall not adversely affect the quality of care rendered to any beneficiary, patient, or resident, or the accuracy of any claims submitted to any Federal health care program.

G. Notification of Government Investigation or Legal Proceeding

Within 30 days after discovery, PAH shall notify OIG, in writing, of any ongoing investigation or legal proceeding known to PAH conducted or brought by a governmental entity or its agents involving an allegation that PAH has committed a crime or has engaged in fraudulent activities. This notification shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding. PAH shall also provide written notice to OIG within 30 days after the resolution of the matter, and shall provide OIG with a description of the findings and/or results of the proceedings, if any.

H. Reporting

1. Overpayments

a. *Definition of Overpayments.* For purposes of this Agreement, an “Overpayment” shall mean the amount of money PAH has received in excess of the amount due and payable under any Federal health care program requirements.

b. *Reporting of Overpayments.* If, at any time, PAH identifies or learns of any Overpayment, PAH shall notify the payor (e.g., Medicare fiscal intermediary or carrier) within 30 days after identification of the Overpayment and take remedial steps within 60 days after identification (or such additional time as may be agreed to by the payor) to correct the problem, including preventing the underlying problem and the Overpayment from recurring. Also, within 30 days after identification of the Overpayment, PAH shall repay the Overpayment to the appropriate payor to the extent such Overpayment has been quantified. If not yet quantified within 30 days after identification, PAH shall notify the payor at that time of its efforts to quantify the Overpayment amount along with a schedule of when such work is expected to be completed. Notification and repayment to the payor shall be done in accordance with the payor’s policies, and for Medicare contractors shall include the information contained on the Overpayment Refund Form, provided as Appendix A to this Agreement. Notwithstanding the above, notification and repayment of any Overpayment amount that routinely is reconciled or adjusted pursuant to policies and procedures established by the payor should be handled in accordance with such policies and procedures.

2. Reportable Events.

a. *Definition of Reportable Event.* For purposes of this Agreement, a “Reportable Event” means anything that involves:

- i. a substantial Overpayment; or
- ii. a matter that a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable to any Federal health care program for which penalties or exclusion may be authorized.

A Reportable Event may be the result of an isolated event or a series of occurrences.

b. *Reporting of Reportable Event.* If PAH determines (after a reasonable opportunity to conduct an appropriate review or investigation of the allegations) through any means that there is a Reportable Event, PAH shall notify OIG, in writing, within 30 days after making the determination that the Reportable Event exists. The report to OIG shall include the following information:

i. if the Reportable Event results in an Overpayment, the report to OIG shall be made at the same time as the notification to the payor required in Section III.H.1, and shall include all of the information on the Overpayment Refund Form, as well as:

(A) the payor's name, address, and contact person to whom the Overpayment was sent; and

(B) the date of the check and identification number (or electronic transaction number) by which the Overpayment was repaid/refunded;

ii. a complete description of the Reportable Event, including the relevant facts, persons involved, and legal and Federal health care program authorities implicated;

iii. a description of PAH's actions taken to correct the Reportable Event; and

iv. any further steps PAH plans to take to address the Reportable Event and prevent it from recurring.

I. Third Party Billing

1. **Current Contract with Third Party Biller.** If PAH presently contracts with a third party billing company to submit claims to the Federal health care programs, PAH represents that it does not have an ownership or control interest (as defined in 42 U.S.C. § 1320a-3(a)(3)) in the third party billing company and is not employed by, and does not act as a consultant to, the third party billing company.

If PAH intends to obtain an ownership or control interest (as defined in 42 U.S.C. § 1320a-3(a)(3)) in, or become employed by, or become a consultant to, any third party billing company during the term of this Agreement, PAH shall notify the OIG 30 days prior to any such proposed involvement.

Within 90 days after the Effective Date, PAH shall obtain (and provide to the OIG in the Implementation Report) a certification from the third party billing company that the company:

- a. is presently in compliance with all Federal health care program requirements as they relate to the submission of claims to Federal health care programs;
- b. has a policy of not employing any person who is excluded, debarred, suspended, or otherwise ineligible to participate in Medicare or other Federal health care programs to perform any duties related directly or indirectly to the preparation or submission of claims to Federal health care programs; and
- c. provides the required training in accordance with Section III.D of the Agreement for those employees involved in the preparation and submission of claims to Federal health care programs.

If PAH contracts with a new third party billing company during the term of this Agreement, PAH shall, within 30 days of entering into such contract, obtain and send to the OIG the certification described in this Section III.I.1.

IV. NEW BUSINESS UNITS OR LOCATIONS

In the event that, after the Effective Date, PAH changes locations or sells, closes, purchases, or establishes a new business unit or location related to the furnishing of items or services that may be reimbursed by Federal health care programs, PAH shall notify the OIG of this fact as soon as possible, but no later than 30 days after the date of change of location, sale, closure, purchase, or establishment. This notification shall include the address of the new business unit or location, phone number, fax number, Medicare and Medicaid provider numbers, provider identification number, and/or supplier number, and the corresponding contractor's name and address that issued each number. Each new business unit or location and

all Covered Persons at each new business unit or location shall be subject to the applicable requirements in this Agreement.

Prior to PAH becoming an employee or contractor with another party related to the furnishing of items or services that may be reimbursed by Federal health care programs, PAH shall notify that party of this Agreement. This notification shall include a copy of the Agreement, a statement indicating the remaining term of the Agreement, and a summary of PAH's obligations under the Agreement. In addition, PAH shall notify the OIG of such relationship in its next Annual Report.

V. REPORTS

A. Implementation Report

Within 120 days after the Effective Date, PAH shall submit a written report to OIG summarizing the status of its implementation of the requirements of this Agreement (Implementation Report). The Implementation Report shall, at a minimum, include:

1. the Compliance Contact's name, address, and phone number, a description of any other job responsibilities performed by the Compliance Contact, and the date the Compliance Contact was appointed;
2. a copy of the notice PAH posted in its office as required by Section III.B, a description of where the notice is posted, and the date the notice was posted;
3. a copy of the written Policies and Procedures required by Section III.C of this Agreement and the date these Policies and Procedures were implemented and distributed;
4. a copy of the general procedures relating to the management and accountability of Vaccines required by Section III.E;
5. a copy of all training materials used for the training session(s) required by Section III.D, a description of the training, including a summary of the topics covered, the length of each session, and a schedule of when the training session(s) were held;
6. a description of PAH's process to screen Covered Persons to determine if they are ineligible;

7. a summary of personnel actions (other than hiring) taken pursuant to Section III.F, the name, title, and responsibilities of any person who is determined to be an Ineligible Person under Section III.F, and the actions taken in response to the obligations set forth in Section III.F;

8. a list of all PAH's locations (including locations and mailing addresses), the corresponding name under which each location is doing business, the corresponding phone numbers and fax numbers, each location's Medicare provider number(s), provider identification number(s), and/or supplier number(s), and the name and address of each contractor to which PAH currently submits claims;

9. if PAH became an employee or contractor with another party related to the furnishing of items or services that may be reimbursed by Federal health care programs, PAH shall inform the OIG of the name, location, relationship, and its responsibilities with respect to PAH's employment or contract;

10. a certification by the Compliance Contact that:

a. the written Policies and Procedures required by Section III.C of this Agreement have been developed, are being implemented, and have been distributed to all Covered Persons; and that all Covered Persons have executed the written Policies and Procedures certification in accordance with the timeframe required by Section III.C of this Agreement;

b. all Covered Persons have completed the applicable training required by Section III.D of this Agreement; and that all Covered Persons have executed the applicable training certification(s) in accordance with the timeframe required by Section III.D of this Agreement;

c. all owners, officers, directors, associates, employees, contractors, and agents that were hired or engaged since the execution of the Agreement were screened against the Exclusion Lists and asked to disclose if they are excluded, debarred, suspended, or are otherwise considered an Ineligible Person, prior to entering into their relationship with PAH, as required by Section III.F of this Agreement;

d. all current owners, officers, directors, associates, employees, contractors, and agents of PAH were screened against the Exclusion Lists within 90 days after the Effective Date of this Agreement, as required by Section III.F of this Agreement and the date(s) of the screening; and

e. PAH has complied with the applicable Federal health care program requirements relating to the management and accountability of Vaccines.

11. a certification signed by the Compliance Contact certifying (a) to the best of his or her knowledge, except as otherwise described in the Implementation Report, PAH is in compliance with all of the requirements of this Agreement and (b) he or she has reviewed the Implementation Report and has made a reasonable inquiry regarding its content and believes that the information is accurate and truthful.

B. Annual Reports

PAH shall submit to the OIG Annual Reports with respect to the status of and findings regarding its compliance activities for each of the three one-year reporting periods beginning on the Effective Date of the Agreement. (The one-year period covered by each Annual Report shall be referred to as "the Reporting Period"). The first Annual Report shall be received by the OIG no later than 60 days after the end of the first Reporting Period. Subsequent Annual Reports shall be received by the OIG no later than the anniversary date of the due date of the first Annual Report.

Each Annual Report shall include:

1. any change in the name, address, phone number, or job responsibilities of PAH's Compliance Contact;
2. any changes to the posted notice and the reason for such changes;
3. a copy of any new compliance-related Policies and Procedures;
4. a summary of any changes or amendments to the written Policies and Procedures required by Section III.C and the reason(s) for such changes (e.g., change in contractor policies);

5. a summary of any changes or amendments to the general procedures relating to the management and accountability of Vaccines required by Section III.E;
6. a copy of all training materials used for the training session(s) required by Section III.D (to the extent they have not already been provided as part of the Implementation Report); a description of the training, including a summary of the topics covered; the length of each session; and a schedule of when the training session(s) was held;
7. a description of PAH's process to screen Covered Persons to determine if they are ineligible (to the extent it has changed from the Implementation Report);
8. a summary of personnel actions/other than hiring taken pursuant to Section III.F; the name, titles, and responsibilities of any person who is determined to be an Ineligible Person under Section III.F; and PAH's actions taken in response to the obligations set forth in Section III.F;
9. a summary describing any ongoing investigation or legal proceeding required to have been reported pursuant to Section III.G. The summary shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding;
10. a summary of Reportable Events (as defined in Section III.H) identified during the Reporting Period and the status of any corrective and preventative action relating to all such Reportable Events;
11. a report of the aggregate Overpayments that have been returned to the Federal health care programs. Overpayment amounts shall be broken down into the following categories: Medicare, Medicaid, and other Federal health care programs;
12. a description of all changes to the most recently provided list of PAH's locations (including addresses) as required by Section IV. Include the corresponding phone numbers, fax numbers, each location's Medicare provider number(s), provider identification number(s), and/or supplier number(s), and the name and address of the contractor that issued each number;

13. if PAH became an employee or contractor with another party related to the furnishing of items or services that may be reimbursed by Federal health care programs, PAH shall inform the OIG of the name, location, relationship, and its responsibilities with respect to PAH's employment or contract;

14. a certification, where appropriate, by the Compliance Contact that certifies that:

a. the written Policies and Procedures have been reviewed during the Reporting Period, as required by Section III.C of this Agreement, and that all Covered Persons have executed the written Policies and Procedures certification in accordance with the timeframe required by Section III.C of this Agreement;

b. all Covered Persons have completed the applicable training required by Section III.D of this Agreement and that all Covered Persons have executed the applicable training certification(s) in accordance with the timeframe required by Section III.D of this Agreement;

c. all owners, officers, directors, associates, employees, contractors, and agents that were hired, engaged, or otherwise involved with PAH during the Reporting Period have been screened against the Exclusion Lists and asked to disclose if they are excluded, debarred, suspended, or are otherwise considered an Ineligible Person, prior to entering into their relationship with PAH, as required by Section III.F of this Agreement;

d. all owners, officers, directors, associates, employees, contractors, and agents (employed, engaged, or otherwise involved with PAH for the entire Reporting Period) were screened against the Exclusion Lists during the Reporting Period, in accordance with Section III.F of this Agreement and the date(s) they were screened;

e. PAH has complied with its obligations under the Settlement Agreement: (1) not to resubmit to any Federal health care program payors any previously denied claims related to the Covered Conduct addressed in the Settlement Agreement, and not to appeal any such denials of claims; (2)

not to charge to or otherwise seek payment from Federal or state payors for unallowable costs (as defined in the Settlement Agreement); and (3) to identify and adjust any past charges or claims for unallowable costs; and

f. PAH has complied with the applicable Federal health care program requirements relating to the management and accountability of Vaccines.

15. a certification signed by the Compliance Contact certifying that (a) to the best of his or her knowledge, except as otherwise described in the applicable Report, PAH is in compliance with all of the requirements of this Agreement and (b) he or she has reviewed the Annual Report and has made a reasonable inquiry regarding its content and believes that the information is accurate and truthful.

C. Designation of Information

PAH shall clearly identify any portions of its submissions that it believes are trade secrets, or information that is commercial or financial and privileged or confidential, and therefore potentially exempt from disclosure under the Freedom of Information Act (FOIA), 5 U.S.C. § 552. PAH shall refrain from identifying any information as exempt from disclosure if that information does not meet the criteria for exemption from disclosure under FOIA.

VI. NOTIFICATIONS AND SUBMISSION OF REPORTS

Unless otherwise stated subsequent to the execution of this Agreement, all notifications and reports required under the terms of this Agreement shall be submitted to the following:

For the OIG: Administrative and Civil Remedies Branch
Office of Counsel to the Inspector General
Office of Inspector General
U.S. Department of Health and Human Services
Cohen Building, Room 5527
330 Independence Avenue, S.W.
Washington, DC 20201
Telephone: (202) 619-2078
Facsimile: (202) 205-0604

For PAH: Lori Violette
Compliance Contact
Pediatric and Adolescent Healthcare
400 Main Street
Ansonia, CT 06401
Telephone: (203) 735-9536

Unless otherwise specified, all notifications and reports required by this Agreement may be made by certified mail, overnight mail, hand delivery, or other means, provided that there is proof that such notification was received. For purposes of this requirement, internal facsimile confirmation sheets do not constitute proof of receipt.

VII. OIG INSPECTION, AUDIT, AND REVIEW RIGHTS

In addition to any other rights the OIG may have by statute, regulation, or contract, the OIG or its duly authorized representative(s) may examine or request copies of PAH's books, records, and other documents and supporting materials and/or conduct on-site reviews of any of PAH's locations for the purpose of verifying and evaluating: (1) PAH's compliance with the terms of this Agreement; and (2) PAH's compliance with the requirements of the Federal health care programs in which it participates. The documentation described above shall be made available by PAH to the OIG or its duly authorized representative(s) at all reasonable times for inspection, audit, or reproduction. Furthermore, for purposes of this provision, the OIG or its duly authorized representative(s) may interview any of PAH's employees, contractors, or agents who consent to be interviewed at the individual's place of business during normal business hours or at such other place and time as may be mutually agreed upon between the individual and the OIG. PAH agrees to assist the OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon the OIG's request. PAH's employees may elect to be interviewed with or without a representative of PAH present.

VIII. DOCUMENT AND RECORD RETENTION

PAH shall maintain for inspection all documents and records relating to reimbursement from the Federal health care programs, or to compliance with this Agreement, for four years (or longer if otherwise required by law).

IX. DISCLOSURES

Consistent with HHS's Freedom of Information Act (FOIA) procedures, set forth in 45 C.F.R. Part 5, the OIG shall make a reasonable effort to notify PAH prior to any release by the OIG of information submitted by PAH pursuant to its obligations under this Agreement and identified upon submission by PAH as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, PAH shall have the rights set forth at 45 C.F.R. § 5.65(d).

X. BREACH AND DEFAULT PROVISIONS

PAH is expected to fully and timely comply with all of its Agreement obligations.

A. Stipulated Penalties for Failure to Comply with Certain Obligations

As a contractual remedy, PAH and the OIG hereby agree that failure to comply with certain obligations set forth in this Agreement (unless a timely written request for an extension has been requested and approved in accordance with Section B below) may lead to the imposition of the following monetary penalties (hereinafter referred to as "Stipulated Penalties") in accordance with the following provisions.

1. A Stipulated Penalty of \$750 (which shall begin to accrue on the day after the date the obligation became due) for each day PAH fails to:

- a. have a Compliance Contact in accordance with the requirements of Section III.A;
- b. establish and/or post a notice in accordance with the requirements of Section III.B;
- c. establish, implement, maintain, distribute, and/or update the written Policies and Procedures in accordance with the requirements of Section III.C;
- d. establish and implement a training program in accordance with the requirements of Section III.D;

e. obtain a certification from the third party biller, send the third party biller certification to the OIG in accordance with the requirements of Section III.I, or notify the OIG within 30 days prior to PAH obtaining an ownership or control interest (as defined in 42 U.S.C. § 1320a-3(a)(3)) in, or becoming employed by, or becoming a consultant to, any third party billing company;

f. obtain and/or maintain the following documentation: Policies and Procedures certifications in accordance with the requirements of Section III.C, training certification(s) in accordance with the requirements of Section III.D, and/or documentation of screening and disclosure requirements in accordance with the requirements of Section III.F.2;

g. screen current or prospective owners, officers, directors, associates, employees, contractors, or agents in accordance with the requirements of Section III.F; or require owners, officers, directors, associates, employees, contractors, or agents to disclose if they are debarred, excluded, suspended, or are otherwise considered an Ineligible Person in accordance with the requirements of Section III.F; or

h. notify the OIG of a Government investigation or legal proceeding, in accordance with the requirements of Section III.G.

2. A Stipulated Penalty of \$1,000 (which shall begin to accrue on the day after the date the obligation became due) for each day PAH fails to submit the Implementation Report or Annual Reports to the OIG in accordance with the requirements of Section V by the deadlines for submission.

3. A Stipulated Penalty of \$750 for each day PAH fails to grant access to the information or documentation as required in Section VII. (This Stipulated Penalty shall begin to accrue on the date PAH fails to grant access.)

4. A Stipulated Penalty of \$5,000 for each false certification submitted by or on behalf of PAH as part of its Implementation Report, Annual Reports, additional documentation to a report (as requested by the OIG), or as otherwise required by this Agreement.

5. A Stipulated Penalty of \$750 for each day PAH fails to comply fully and adequately with any obligation of this Agreement. OIG shall provide notice (Notice) to PAH stating the specific grounds for its determination that PAH has failed to comply fully and adequately with the Agreement obligation(s) at issue and steps the PAH shall take to comply with the Agreement. (This Stipulated Penalty shall begin to accrue 10 days after the date PAH receives this Notice from the OIG of the failure to comply.) A Stipulated Penalty as described in this Subsection shall not be demanded for any violation for which the OIG has sought a Stipulated Penalty under Subsections 1-4 of this Section.

B. Timely Written Requests for Extensions

PAH may, in advance of the due date, submit a timely written request for an extension of time to perform any act or file any notification or report required by this Agreement. Notwithstanding any other provision in this Section, if the OIG grants the timely written request with respect to an act, notification, or report, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until one day after PAH fails to meet the revised deadline set by OIG. Notwithstanding any other provision in this Section, if the OIG denies such a timely written request, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until three business days after PAH receives the OIG's written denial of such request or the original due date, whichever is later. A "timely written request" is defined as a request in writing received by the OIG at least five business days prior to the date by which any act is due to be performed or any notification or report is due to be filed.

C. Payment of Stipulated Penalties.

1. Demand Letter. Upon a finding that PAH has failed to comply with any of the obligations described in Section X.A and after determining that Stipulated Penalties are appropriate, the OIG shall notify PAH of: (a) PAH's failure to comply; and (b) the OIG's exercise of its contractual right to demand payment of the Stipulated Penalties (this notification is referred to as the "Demand Letter").

2. Response to Demand Letter. Within 10 days of the receipt of the Demand Letter, PAH shall either: (a) cure the breach to the OIG's satisfaction and pay the applicable Stipulated Penalties; or (b) send in writing to the OIG a request for a hearing before an HHS

administrative law judge (ALJ) to dispute the OIG's determination of noncompliance, pursuant to the agreed upon provisions set forth below in Section X.E. In the event PAH elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until PAH cures, to the OIG's satisfaction, the alleged breach in dispute. Failure to respond to the Demand Letter in one of these two manners within the allowed time period shall be considered a material breach of this Agreement and shall be grounds for exclusion under Section X.D.

3. Form of Payment. Payment of the Stipulated Penalties shall be made by certified or cashier's check, payable to: "Secretary of the Department of Health and Human Services," and submitted to the OIG at the address set forth in Section VI.

4. Independence from Material Breach Determination. Except as set forth in Section X.D.1.c, these provisions for payment of Stipulated Penalties shall not affect or otherwise set a standard for the OIG's decision that PAH has materially breached this Agreement, which decision shall be made at the OIG's discretion and shall be governed by the provisions in Section X.D, below.

D. Exclusion for Material Breach of this Agreement

1. Definition of Material Breach. A material breach of this Agreement means:

- a. a failure by PAH to report a Reportable Event, take corrective action, and make the appropriate refunds, as required in Section III.H;
- b. a repeated or flagrant violation of the obligations under this Agreement, including, but not limited to, the obligations addressed in Section X.A; or
- c. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with Section X.C.

2. Notice of Material Breach and Intent to Exclude. The parties agree that a material breach of this Agreement by PAH constitutes an independent basis for PAH's exclusion from participation in the Federal health care programs. Upon a determination by the OIG that

PAH has materially breached this Agreement and that exclusion is the appropriate remedy, the OIG shall notify PAH of: (a) PAH's material breach; and (b) the OIG's intent to exercise its contractual right to impose exclusion (this notification is hereinafter referred to as the "Notice of Material Breach and Intent to Exclude").

3. Opportunity to Cure. PAH shall have 30 days from the date of receipt of the Notice of Material Breach and Intent to Exclude to demonstrate to the OIG's satisfaction that:

- a. PAH is in compliance with the obligations of the Agreement cited by the OIG as being the basis for the material breach;
- b. the alleged material breach has been cured; or
- c. the alleged material breach cannot be cured within the 30-day period, but that: (i) PAH has begun to take action to cure the material breach; (ii) PAH is pursuing such action with due diligence; and (iii) PAH has provided to the OIG a reasonable timetable for curing the material breach.

4. Exclusion Letter. If at the conclusion of the 30-day period, PAH fails to satisfy the requirements of Section X.D.3, the OIG may exclude PAH from participation in the Federal health care programs. The OIG shall notify PAH in writing of its determination to exclude PAH (this letter shall be referred to hereinafter as the "Exclusion Letter"). Subject to the Dispute Resolution provisions in Section X.E, below, the exclusion shall go into effect 30 days after the date of PAH's receipt of the Exclusion Letter. The exclusion shall have national effect and shall also apply to all other Federal procurement and nonprocurement programs. Reinstatement to program participation is not automatic. After the end of the period of exclusion, PAH may apply for reinstatement, by submitting a written request for reinstatement in accordance with the provisions at 42 C.F.R. §§ 1001.3001-.3004.

E. Dispute Resolution

1. Review Rights. Upon the OIG's delivery to PAH of its Demand Letter or of its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under this Agreement, PAH shall be afforded certain review rights comparable to the ones that are provided in 42 U.S.C. § 1320a-7(f) and 42 C.F.R. Part 1005

as if they applied to the Stipulated Penalties or exclusion sought pursuant to this Agreement. Specifically, the OIG's determination to demand payment of Stipulated Penalties or to seek exclusion shall be subject to review by an HHS ALJ and, in the event of an appeal, the HHS Departmental Appeals Board (DAB), in a manner consistent with the provisions in 42 C.F.R. § 1005.2-1005.21. Notwithstanding the language in 42 C.F.R. § 1005.2(c), the request for a hearing involving Stipulated Penalties shall be made within 10 days after the receipt of the Demand Letter and the request for a hearing involving exclusion shall be made within 25 days after receipt of the Exclusion Letter.

2. Stipulated Penalties Review. Notwithstanding any provision of Title 42 of the United States Code or Chapter 42 of the Code of Federal Regulations, the only issues in a proceeding for Stipulated Penalties under this Agreement shall be: (a) whether PAH was in full and timely compliance with the obligations of this Agreement for which the OIG demands payment; and (b) the period of noncompliance. PAH shall have the burden of proving its full and timely compliance and the steps taken to cure the noncompliance, if any. The OIG shall not have the right to appeal to the DAB an adverse ALJ decision related to Stipulated Penalties. If the ALJ agrees with the OIG with regard to a finding of a breach of this Agreement and orders PAH to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless PAH requests review of the ALJ decision by the DAB. If the ALJ decision is properly appealed to the DAB and the DAB upholds the determination of the OIG, the Stipulated Penalties shall become due and payable 20 days after the DAB issues its decision.

3. Exclusion Review. Notwithstanding any provision of Title 42 of the United States Code or Chapter 42 of the Code of Federal Regulations, the only issues in a proceeding for exclusion based on a material breach of this Agreement shall be:

- a. whether PAH was in material breach of this Agreement;
- b. whether such breach was continuing on the date of the Exclusion Letter; and
- c. whether the alleged material breach could not have been cured within the 30 day period, but that: (i) PAH had begun

to take action to cure the material breach within that period; (ii) PAH has pursued and is pursuing such action with due diligence; and (iii) PAH provided to the OIG within that period a reasonable timetable for curing the material breach and PAH has followed the timetable.

For purposes of the exclusion herein, exclusion shall take effect only after an ALJ decision favorable to the OIG, or, if the ALJ rules for PAH, only after a DAB decision in favor of the OIG. PAH's election of its contractual right to appeal to the DAB shall not abrogate the OIG's authority to exclude PAH upon the issuance of an ALJ's decision in favor of the OIG. If the ALJ sustains the determination of the OIG and determines that exclusion is authorized, such exclusion shall take effect 20 days after the ALJ issues such a decision, notwithstanding that PAH may request review of the ALJ decision by the DAB. If the DAB finds in favor of the OIG after an ALJ decision adverse to the OIG, the exclusion shall take effect 20 days after the DAB decision. PAH shall waive its right to any notice of such exclusion if a decision upholding the exclusion is rendered by the ALJ or DAB. If the DAB finds in favor of PAH, PAH shall be reinstated effective on the date of the original exclusion.

4. Finality of Decision. The review by an ALJ or DAB provided for above shall not be considered to be an appeal right arising under any statutes or regulations. Consequently, the parties to this Agreement agree that the DAB's decision (or the ALJ's decision if not appealed) shall be considered final for all purposes under this Agreement.

XI. EFFECTIVE AND BINDING AGREEMENT

Consistent with the provisions in the Settlement Agreement pursuant to which this Agreement is entered, and into which this Agreement is incorporated, PAH and the OIG agree as follows:

A. This Agreement shall be binding on the successors, assigns, and transferees of PAH.

B. This Agreement shall become final and binding on the date the final signature is obtained on the Agreement.

C. Any modifications to this Agreement shall be made with the prior written consent of the parties to this Agreement.

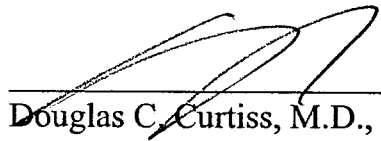
D. The OIG may agree to a suspension of PAH's obligations under this Agreement in the event of PAH's cessation of participation in Federal health care programs. If PAH withdraws from participation in Federal health care programs and is relieved of its Agreement obligations by the OIG, PAH shall notify the OIG 30 days in advance of PAH's intent to reapply as a participating provider or supplier with any Federal health care program. Upon receipt of such notification, the OIG shall evaluate whether the Agreement shall be reactivated or modified.

E. All requirements and remedies set forth in this Agreement are in addition to, and do not effect, (1) PAH's responsibility to follow all applicable Federal health care program requirements or (2) the Government's right to impose appropriate remedies for failure to follow applicable program requirements.

F. The undersigned PAH signatory represents and warrants that he is authorized to execute this Agreement. The undersigned OIG signatory represents that he is signing this Agreement in his official capacity and that he is authorized to execute this Agreement.

IN WITNESS WHEREOF, the parties hereto affix their signatures:

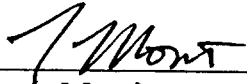
FOR PEDIATRIC AND ADOLESCENT HEALTHCARE



Douglas C. Curtiss, M.D., F.A.A.P.
President

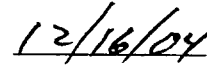
12/8/04
Date

**FOR THE OFFICE OF INSPECTOR GENERAL OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES**



Lewis Morris

Chief Counsel to the Inspector General
Office of Inspector General
U.S. Department of Health and Human Services



Date

APPENDIX A

OVERPAYMENT REFUND

TO BE COMPLETED BY MEDICARE CONTRACTOR

Date: _____

Contractor Deposit Control # _____

Date of Deposit: _____

Contractor Contact Name: _____

Phone # _____

Contractor Address: _____

Contractor Fax: _____

TO BE COMPLETED BY PROVIDER/PHYSICIAN/SUPPLIER

Please complete and forward to Medicare Contractor. This form, or a similar document containing the following information, should accompany every voluntary refund so that receipt of check is properly recorded and applied.

PROVIDER/PHYSICIAN/SUPPLIER NAME _____

ADDRESS _____

PROVIDER/PHYSICIAN/SUPPLIER # _____

CHECK NUMBER# _____

CONTACT PERSON: _____

PHONE # _____

\$ _____ CHECK DATE _____ AMOUNT OF CHECK

REFUND INFORMATION

For each Claim, provide the following:

Patient Name _____

HIC # _____

Medicare Claim Number _____

Claim Amount Refunded \$ _____

Reason Code for Claim Adjustment: _____ (Select reason code from list below. Use one reason per claim)

(Please list all claim numbers involved. Attach separate sheet, if necessary)

Note: If Specific Patient/HIC/Claim #/Claim Amount data not available for all claims due to Statistical Sampling, please indicate methodology and formula used to determine amount and reason for overpayment: _____

For Institutional Facilities Only:

Cost Report Year(s) _____

(If multiple cost report years are involved, provide a breakdown by amount and corresponding cost report year.)

For OIG Reporting Requirements:

Do you have a Corporate Integrity Agreement with OIG? _____

Yes

No

Reason Codes:

Billing/Clerical Error

01 - Corrected Date of Service

02 - Duplicate

03 - Corrected CPT Code

04 - Not Our Patient(s)

05 - Modifier Added/Removed

06 - Billed in Error

07 - Corrected CPT Code

MSP/Other Payer Involvement

08 - MSP Group Health Plan Insurance

09 - MSP No Fault Insurance

10 - MSP Liability Insurance

11 - MSP, Workers Comp. (Including

Black Lung

12 - Veterans Administration

Miscellaneous

13 - Insufficient Documentation

14 - Patient Enrolled in an HMO

15 - Services Not Rendered

16 - Medical Necessity

17 - Other (Please Specify) _____